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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/07/2006

Niels Joergen Madsen

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,916	Applicant(s) MADSEN ET AL.
	Examiner Isis Ghali	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2011.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
4a) Of the above claim(s) 2-5, 14-20, 22-25 and 27-36 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 6-13, 21, 26 and 37-42 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' response filed 05/23/2011 to the non-final office action mailed 03/01/2011.

Claims 1-42 are pending.

Claims 2-5, 14-20, 22-25, 27-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/15/2009.

Claims 1, 6-13, 21, 26 and 37-42 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 6-13, 21, 26, 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48858 ('858, IDS filed 07/24/2006) in view of JP 07-070545 ('545, previously cited) and GB 1431683 ('683, previously cited).

Applicant Claims

Applicants' currently amended claim 1 is directed to a composition comprising:

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- a) one or more hydrogel-forming hydrophilic homopolymers or heteropolymers and
- b) one or more amphiphilic block-copolymers comprising:
 - (i) one or more hydrophobic polymer blocks incompatible with the hydrogel-forming hydrophilic homopolymers or heteropolymers and
 - (ii) one or more hydrophilic polymer blocks, including a hydrophilic end block, compatible with the hydrogel-forming hydrophilic homopolymers or heteropolymers.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

WO '858 teaches pressure sensitive adhesive composition for application to human or animal skin comprising polyvinyl pyrrolidones polymer (PVP) or PVP copolymer, and block copolymer comprising styrene to improve the rate of absorption of water and improve integrity and wet tack of the adhesive composition on wet skin (abstract). PVP has capability to absorb water (page 7, lines 13-16), i.e. hydrogel forming polymer. The composition further comprises hydrocolloid selected from polyethylene glycol, which reads on plasticizer claimed by claim 8 (page 9, line 7).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although WO '858 teaches the adhesive composition comprises block copolymer comprising styrene to improve the rate of absorption of water and improve integrity and wet tack of the adhesive composition on wet skin, however, the reference does not explicitly teach amphiphilic block-copolymers comprising hydrophobic polymer blocks and hydrophilic end block polymer as instantly claimed by claim 1.

JP '545 teaches adjustable pressure sensitive adhesive suitable for medicine delivery comprising copolymer having in the polymer molecule hydrophilic part such as polyethylene glycol and hydrophobic part such as styrene polymers. The pressure sensitive adhesive has adjustable pressure sensitive adhesiveness. The teaching of the reference encompasses all copolymer configuration including diblock and triblock copolymers. Both polymer do not dissolve in each other and suitable for drug delivery. (See abstract; paragraphs 007-0014).

GB '683 teaches triblock as well as diblock copolymers having low glass temperature comprising hydrophobic styrene B polymers and hydrophilic polyethylene A polymers. The block copolymers have high water absorption capacity and can be used as surfactant and emulsifier. The references teaches BA and BAB block copolymers wherein block B is the hydrophobic and block A is the hydrophilic, hence BA polymer has hydrophilic end block. The molecular weight of hydrophobic block B is between 1,000 and 500,000 and molecular weight of hydrophilic block A is between 1,000 and 500,000. (See page 1, lines 46-90; page 2, lines 54-57, 85-100, 130; page 3, lines 1-2, 76-86; page 4, lines 109-115).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide pressure sensitive adhesive composition for application to human or animal skin comprising polymer or copolymer PVP and block copolymer comprising styrene to improve the rate of absorption of water as taught by WO '858, and replace the block copolymer comprising styrene with copolymer comprising hydrophobic block and hydrophilic block as taught by JP '545 and further use block copolymer having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 as taught by GB '683. One would have been motivated to do so because WO '858 desired to improve water absorption and because JP '545 teaches that copolymers having hydrophilic and hydrophilic polymers in the molecules are suitable for medicinal delivery and provides adjustable pressure sensitive adhesiveness, and because GB '683 teaches that block copolymers having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 have low glass temperature, have high water absorption capacity and can be used as surfactant and emulsifier. One would reasonably expect formulating pressure sensitive adhesive composition for application to human or animal skin comprising polymer or copolymer of PVP and block copolymers having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 wherein the adhesive has adjustable adhesiveness, high

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water absorption capacity and can be used as surfactant and emulsifier therefore provide improved absorption properties and improved medicinal delivery from the adhesive.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

5. Applicant's arguments filed 05/23/2011 have been fully considered but they are not persuasive.

Applicants argue that WO '858 teaches the block-copolymer component that must be "a physically cross-linked elastomer selected from block-copolymers comprising styrene and one or more butadienes". Since the rejection would "replace" the WO '858 block copolymer with one that does not contain "one or more butadienes" (i.e., the diblock (AB) amphiphilic copolymer of GB '683), it would effectively destroy the invention on which WO '858 is based and, therefore, the rejection is untenable.

In response to this argument, it is the examiner position that it is obvious to replace a block copolymer with another block copolymer known to have the same function because JP '545 teaches the equivalency between styrene-butadiene copolymer and copolymer having hydrophobic and hydrophilic polymers. It is *prima facie* obvious to substitute one functional equivalent for another functionally equivalent

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member. In KSR, the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,” USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” USPQ2d at 1395. The Supreme Court stated that there are “[t]hree cases decided after Graham [that] illustrate this doctrine.” 82 USPQ2d at 1395. (1) “In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” USPQ2d at 1395. (2) “In *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation.” *Id.* USPQ2d at 1395. (3) “[I]n *Sakraida v. AG Pro, Inc.*, the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious. The Supreme Court further stated that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a

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person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. USPQ2d at 1396.

It is further noticed that the rejection is based on combination of WO '858, JP '545 and GB '683, and applicants completely ignore the teaching of JP '545 that teaches block copolymer comprising styrene-butadiene copolymer and copolymer comprising hydrophilic and hydrophobic polymers (paragraph 0008), and further teaches the copolymers having hydrophilic and hydrophilic polymers in the molecules are suitable for medicinal delivery and provides adjustable pressure sensitive adhesiveness. WO '585 does not exclude other polymers other than butadiene. One having ordinary skill in the art would have to replace the block copolymer comprising styrene with copolymer comprising hydrophobic block and hydrophilic block as taught by JP '545 and further use block copolymer having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 as taught by GB '683. GB '683 is relied upon for teaching block copolymers having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 for the benefit of having low glass temperature of the copolymer and high water absorption capacity. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

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208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that the references relied on in combination teach away from being so combined. WO '858 teaches an adhesive composition comprising block copolymer comprising styrene and one or more butadienes and the reference teaches away from replacing butadiene component with something else, therefore, the rejection cannot be maintained. The WO '858 requirement for "a physically cross-linked elastomer selected from block-copolymers comprising styrene and one or more butadienes" would have led the skilled artisan away from the "one or more amphiphilic block-copolymers" component as used in the presently claimed invention.

In response to this argument, the examiner position as previously discussed it is obvious to replace or substitute one copolymer with art equivalent copolymer. It is further argued that the references do not teach away because the references are analogous art and are in the field of applicant's endeavor and reasonably pertinent to the particular problem with which the applicant was concerned, which is adhesive for transdermal drug delivery. Further JP '545 teaches equivalency between copolymer taught by WO '858 and copolymer comprising hydrophilic and hydrophobic blocks (amphiphilic copolymer), and teaches the advantage of the amphiphilic copolymer. Therefore it is proper to combine the references and the references do not teach away from each other or from the present invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). "A reference may be said to teach away when a

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person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551,553 (Fed. Cir. 1994).

Applicant is also reminded, that it has been decided by the Courts that even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR, 127 S. Ct. at 1739.3 "Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d at 301; see also *In re Mayne*, 104 F.3d at 1340; according KSR, 127 S. Ct. at 1740. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR, 127 S. Ct. at 1739.3. *In re Best*, 562 F.2d at 1255; *In re Rijckaert*, 9 F.3d at 1532.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are

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evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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